Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the January 2006 list were published in the Federal Register in August 2006.

New Approvals

ANADA Number: 200-395

Pioneer Product:	046-724
Trade Name:	Gentamicin Sulfate Solution
Ingredients:	Gentamicin Sulfate
Sponsor:	Sparhawk Laboratories, Inc.
Approval Date:	July 31, 2006
Status:	Prescription only
Route:	Intrauterine
Species:	Horses
Drug Form:	Liquid (solution)
Concentration:	100 milligrams per milliliter
Indications:	For the control of bacterial infections of the uterus (metritis) in horses and as an aid in improving conception in mares with uterine infections caused by bacteria sensitive to gentamicin.

21CFR 529.1044a

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval, please refer to 21CFR Parts 500 and the related Federal Register notices.

NADA Number: 038-439

Trade Name:	Terramycin® 200 for Fish
Ingredients:	Oxytetracycline dihydrate
Sponsor:	Phibro Animal Health
Approval Date:	June 30, 2006

This application provides for the approval of the dehydrate salt of oxytetracycline in their Type A Medicated Article used in aquaculture feed, a change in concentration in the Type A Medicated Article, and the addition of an indication for control of gaffkemia caused by *Aerococcus viridans* in lobsters.

21CFR 558.450

Change of Sponsor

ANADA Number(s): 200-237

From:	Rhodia UK Ltd
To:	Nicholas Piramal India Ltd. UK 1st Floor, Alpine House, Unit II Honeypot Lane London, NW99RX, England, UK
Drug labeler code:	066112

Actions Taken by FDA Center for Veterinary Medicine

Technical Amendment

The Food and Drug Administration (FDA) is amending the animal drug regulations to remove inactive ingredients from the specifications for an oral suspension and for tablets containing kanamycin, bismuth subcarbonate, and activated attapulgite; and to consolidate and reformat these sections. These actions are being taken to improve the accuracy and readability of the animal drug regulations.

This rule is effective August 3, 2006.

For further information contact: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-4567, e-mail: george.haibel@fda.hhs.gov.

FDA is amending the animal drug regulations in part 520 (21 CFR part 520) in Sec. 520.1204 and 520.1205 to remove aminopentamide hydrogen sulfate and pectin from the specifications for an oral suspension and for tablets containing kanamycin, bismuth subcarbonate, and activated attapulgite. These ingredients have been declared inactive or have been removed from the formulations. In addition, these sections are being reformatted and consolidated. These actions are being taken to improve the accuracy and readability of the animal drug regulations.

Notice(s)

The Food and Drug Administration (FDA) is announcing a public meeting it will hold to present work-in-progress on a method for ranking animal feed contaminants by their relative risks to animal and human health. The relative risk posed by feed contaminants to animal and human health consists of two components, namely health consequence scoring and exposure scoring. At this meeting the agency will describe the methods it plans to use to develop animal and human health consequence scoring for chemical, physical, and biological feed contaminants. At one or more subsequent public meetings, FDA will present information about how the health consequence scoring will be combined with information about the exposure of animals and humans to feed contaminants to determine the relative risks of such contaminants in feed. Date and Time: The public meeting will be held on September 12, 2006, from 9 a.m. to 4:30 p.m. Location: The meeting will be held at the Center for Drug Evaluation and Research Conference Room, third floor, 7519 Standish Pl., Rockville, MD 20855.

You may submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Follow the instructions for submitting comments.

For further information contact: Zoe Gill, Center for Veterinary Medicine (HFV-226), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6867, FAX 240-453-6882, e-mail: zoe.gill@fda.hhs.gov.

You may register by telephone, fax, or e-mail by contacting Nanette Milton, Center for Veterinary Medicine (HFV-200), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6840, FAX 240-453-6880, e-mail: nanette.milton@fda.hhs.gov. Send registration information (including name, title, firm name, address, telephone, and fax number to Nanette Milton. To obtain the registration form via the Internet go to http://www.fda.gov/cvm/AFSS.htm#Meetings. Due to limited meeting space, registration will be required. We strongly encourage early registration.

The Food and Drug Administration (FDA) is announcing the rates and payment procedures for fiscal year (FY) 2007 animal drug user fees. The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Animal Drug User Fee Act of 2003 (ADUFA), authorizes FDA to collect user fees for certain animal drug applications, on certain animal drug products, on certain establishments where such products are made, and on certain sponsors of such animal drug applications and/or investigational animal drug submissions. This notice establishes the fee rates for FY 2007. For FY 2007, the animal drug user fee rates are: $168,600 for an animal drug application; $84,300 for a supplemental animal drug application for which safety or effectiveness data is required; $4,115 for an annual product fee; $51,350 for an annual establishment fee; and $44,850 for an annual sponsor fee. FDA will issue invoices for FY 2007 product, establishment, and sponsor fees by December 30, 2006, and these invoices will be due and payable by January 31, 2007. The application fee rates are effective for applications submitted on or after October 1, 2006, and will remain in effect through September 30, 2007. Applications

will not be accepted to review until FDA has received full payment of application fees and any other animal drug user fees owed.

For further information contact: Visit the FDA Web site at http://www.fda.gov/oc/adufa or contact Robert Miller, Center for Veterinary Medicine (HFV-10), Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, 240-276-9707. For general questions, you may also e-mail the Center for Veterinary Medicine (CVM) at: cvmadufa@fda.gov.

The Food and Drug Administration (FDA) will hold a public meeting October 10, 2006, on FDA-regulated products containing nanotechnology materials, and has opened a docket on FDA-regulated products containing nanotechnology materials. The purpose of the meeting will be to help FDA further its understanding of developments in nanotechnology materials that pertain to FDA-regulated products. FDA is interested in learning about the kinds of new nanotechnology material products under development in the areas of foods (including dietary supplements), food and color additives, animal feeds, cosmetics, drugs and biologics, and medical devices, whether there are new or emerging scientific issues that should be brought to FDA's attention, and any other scientific issues about which the regulated industry, academia, and the interested public may wish to inform FDA concerning the use of nanotechnology materials in FDA-regulated products.

The public meeting will be held October 10, 2006, from 9 a.m. to 5 p.m. Registration: You may register at http://www.fda.gov/nanotechnology/. We will also post the agenda at http://www.fda.gov/nanotechnology/ prior to the meeting.

The public workshop will be held at the Natcher Auditorium, National Institutes of Health Campus, 9000 Rockville Pike, bldg. 45, Bethesda, MD. We will also post the address for the meeting at http://www.fda.gov/nanotechnology/.

Written or electronic comments may be submitted by November 10, 2006. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. All comments should be identified with the docket number, Docket No. 2006N-0107.

For further information contact: Poppy Kendall, Food and Drug Administration (HF-11), 5600 Fishers Lane, Rockville, MD 20857, 301-827-3360, FAX: 301-594-6777, e-mail: poppy.kendall@fda.hhs.gov.

The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry (183) entitled ``Animal Drug User Fees: Fees Exceed Costs Waivers and Reductions.'' The draft guidance explains the procedures FDA expects to use to evaluate waiver requests under the fees exceed costs waiver provision of the Animal Drug User Fee Act of 2003.

Submit written or electronic comments on the draft guidance by October 31, 2006 to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time. Submit written requests for single copies of the draft guidance document to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance document to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http:///www.fda.gov/dockets/ecomments.

For further information contact: Dave Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6967, e-mail: david.newkirk@fda.hhs.gov.

The Minor Use and Minor Species Animal Health Act of 2004 (MUMS act) amended the Federal Food, Drug, and Cosmetic Act (the act) to authorize the U.S. Food and Drug Administration (FDA, the agency) to establish new regulatory procedures that provide incentives intended to make more drugs legally available to veterinarians and animal owners for the treatment of minor animal species and uncommon diseases in major animal species. At this time, FDA is issuing proposed regulations to implement section 572 of the act entitled ``Index of Legally Marketed Unapproved New Animal Drugs for Minor Species.'' These regulations propose administrative procedures and criteria for index listing a new animal drug for use in a minor species. Such indexing provides a basis for legally marketing an unapproved new animal drug intended for use in a minor species.

Submit written or electronic comments on this document by November 20, 2006. Interested persons are requested to submit comments on the information collection provisions by September 21, 2006. You may submit comments, identified by [Docket No. 2006N-0067 and/RIN number 0910-AF67], by any of the following methods:
Electronic Submissions
Submit electronic comments in the following ways: Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Agency Web site: http://www.fda.gov/dockets/ecomments.
Written Submissions
Submit written submissions in the following ways: FAX: 301-827-6870. Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site. All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) for this rulemaking. All comments received may be posted without change to http://www.fda.gov/ohrms/dockets/default.htm, including any personal information provided. Docket: For access to the docket to read background documents or comments received, go to http://www.fda.gov/ohrms/dockets/default.htm and insert the docket number(s), [Docket No. 2006N-0067 and/RIN number 0910-AF67], into the ``Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974.

For further information contact: Andrew Beaulieu, Center for Veterinary Medicine (HFV-50), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9090, e-mail: Andrew.Beaulieu@fda.hhs.gov.

Veterinary Medicine Advisory Committee; Notice of Meeting
This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public. Name of Committee: Veterinary Medicine Advisory Committee. General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.
Date and Time: The meeting will be held on September 25, 2006, from 8:30 a.m. to 5 p.m. Location: DoubleTree Hotel, Plaza Rooms II-III, 1750 Rockville Pike, Rockville, MD. Contact Person: Aleta Sindelar, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9004, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 301-451-2548. Please call the Information Line for up-to-date information on this meeting. Agenda: The committee will discuss and make recommendations on the microbial food safety of an antimicrobial drug application currently under review for use in food-producing animals in accordance with the Center for Veterinary Medicine's guidance for industry 152. The background material for this meeting will be posted on the Internet no later than 1 business day before the meeting at http://www.fda.gov/cvm/default.html. Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 13, 2006. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before September 13, 2006. Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets. FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Aleta Sindelar at least 7 days in advance of the meeting.

Agency Information Collection Activities; Proposed Collection; Comment Request; Medicated Feed Mill License Application—Extension
The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the medicated feed mill licensing system.

Submit written or electronic comments on the collection of information by October 24, 2006. Submit electronic comments on the collection of information to: http://www.fda.gov/dockets/ecomments. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number [Docket No. 2006N-0329].

For further information contact: Denver Presley, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

The Food and Drug Administration (FDA) is proposing to amend its regulations governing drug establishment registration and drug listing. The proposed revisions would reorganize, consolidate, clarify, and modify current regulations concerning who must register establishments and list human drugs, human drugs that are also biological products (including vaccines and allergenic products), and/or human cells, tissues, and cellular and tissue-based products (HCT/Ps), and animal drugs. The proposal describes when and how to register and list and what information must be submitted for registration and listing. In addition, the proposal would make certain changes to the National Drug Code (NDC) system and would require the appropriate NDC number to appear on the labels for drugs subject to the listing requirements. The proposed regulations generally would require the electronic submission of all registration and most listing information. We (FDA) rely on establishment registration and drug listing information for administering many of our programs, such as postmarketing surveillance (including FDA inspections), bioterrorism, drug shortages and availability, and user fee assessments. We are taking this action to use the latest technology to improve our registration and listing system, which would further our goal of protecting the public health. We also believe that the conversion to an electronic system would make the registration and listing processes more efficient and effective for industry and us. We are also taking this action to support the implementation of, for example, the electronic prescribing provisions of the Medicare Prescription Drug, Improvement, and Modernization Act, our rulemaking requiring a bar code on certain drug products, and the DailyMed initiative.

Submit written or electronic comments by November 27, 2006. Submit written comments on the information collection requirements by September 28, 2006 to OMB (see Addresses). See section IX of this document for the proposed effective date and section X for the proposed compliance dates of a final rule based on this document.

Addresses: You may submit comments, identified by Docket No. 2005N-0403 and/RIN 0910-AA49, by any of the following methods:
Electronic Submissions: Submit electronic comments in the following ways: Federal eRulemaking Portal: http://www.regulations.gov. Agency Web site: http://www.fda.gov/dockets/ecomments. Follow the instructions for submitting comments on the agency Web site.
Written Submissions: Submit written submissions in the following ways: FAX: 301-827-6870.
Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail.
Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to http://www.fda.gov/ohrms/dockets/default.htm, including any personal information provided. Docket: For access to the docket to read background documents or comments received, go to http://www.fda.gov/ohrms/dockets/default.htm and insert the docket number(s), Docket No. 2005N-0403 and/RIN 0910-AA49, into the ``Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974.

For further information contact: For information concerning drugs regulated by the Center for Drug Evaluation and Research (CDER): Herbert Gerstenzang or John W. Gardner, Center for Drug Evaluation and Research (HFD-330), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-8920, herbert.gerstenzang@fda.hhs.gov or john.gardner@fda.hhs.gov. For information concerning products regulated by the Center for Biologics Evaluation and Research (CBER): Valerie A. Butler, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210, valerie.butler@fda.hhs.gov. For information concerning animal drugs: Lowell Fried (HFV-212) or Isabel W. Pocurull (HFV-226), Center for Veterinary Medicine (CVM), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-7820 or 240-453-6853, lowell.fried@fda.hhs.gov or isabel.pocurull@fda.hhs.gov.